

JAS DIAGNOSTICS: 510(K) NOTIFICATION

JAN 18 2002

K013912

510(K) SUMMARY

Submitter

Name: Attn: David Johnston
JAS Diagnostics, Inc.
7220 N.W. 58th Street
Miami, FL 33166
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Email: D.Johnston@JASDiagnostics.com

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FDA/CDER/DOE/DMC

Device Name:

Trade Name: JAS Creatine Kinase (CK-NAC) Liquid Reagent
Common Name: Creatine Kinase (CK) Reagent
Classification Name: 21 CFR 862.1215

Predicate Devices:

-Roche Diagnostics CK NAC Reagent for the Roche Cobas Mira analyzers
-Pointe Scientific Creatine Kinase (CK) Reagent (generic)

Device Description:

This Reagent is intended for the in vitro quantitative determination of creatine kinase in human serum.

Summary of the Similarities to the

Intended Use: All devices are intended for the detection of creatine kinase (CK) in human serum on automated chemistry analyzers.

Predicate Devices:

Results Interpretation: Correlation studies on human serum demonstrated acceptable result comparisons between these methods, which all use similar normal ranges.

Discussion and Conclusion:

The JAS Creatine Kinase (CK-NAC) Liquid Reagent's intended use is identical to predicate Devices and it's performance acceptable on the automated chemistry analyzers tested. The JAS CK-NAC Liquid Reagent is therefore substantially equivalent to FDA registered Creatine Kinase (CK) Reagents currently in the market.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Mr. David Johnston
Technical Director
JAS Diagnostics, Inc.
7220 N.W. 58th Street
Miami, FL 33166

JAN 1 8 2002

Re: k013912
Trade/Device Name: Creatine Kinase (CK) Reagent
Regulation Number: 21 CFR 862.1215
Regulation Name: Creatine Phosphokinase/Creatine Kinase or Isoenzymes Test System
Regulatory Class: Class II
Product Code: CGS
Dated: October 22, 2001
Received: November 27, 2001

Dear Mr. Johnston:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

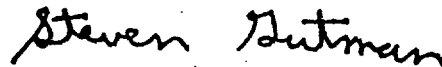
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,

A handwritten signature in black ink that reads "Steven Gutman". The signature is written in a cursive, slightly slanted style.

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): N/A

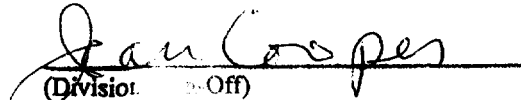
Device Name: Creatine Kinase (CK) REAGENT

K013912

Indications for Use:

Intended for the In Vitro, quantitative determination of creatine kinase (CK) in human serum on automated chemistry analyzers.

Creatine kinase measurements are used in the diagnosis and treatment of myocardial infarction and muscle diseases such as progressive, Duchenne-type muscular dystrophy.


(Division Off)
Division Clinical Laboratory Devices
510(k) N. K013912

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)